1022-80 **Safety and Feasibility of Paclitaxel-Eluting Stents in the Treatment of ST-Elevation Acute Myocardial Infarction**

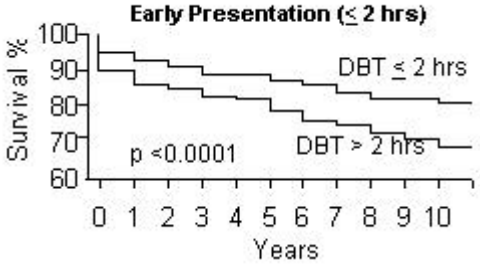
Andrew T. L Ong, Pedro A. Lemos, Angela Hoye, Chourmouzios A. Arampatzis, Francesco Saia, Jiro Aoki, Carlos van Mieghem, Sjoerd H. Hofma, Pieter C. Smits, Willem J. van der Giessen, Georgios Sianos, Eugene McFadden, Pim de Feyter, Patrick W. Serruys, Thoraxcenter, Rotterdam, The Netherlands

Background: Paclitaxel-eluting stents (PES) have been shown to markedly reduce restenosis in elective patients. To date, there have been no studies evaluating their role in the treatment of ST-Elevation Myocardial Infarction.
Method: Paclitaxel-eluting stents have been utilised as the default strategy for all patients at our institution as part of the Taxus-Stent Evaluated At Rotterdam Cardiology Hospital (T-SEARCH) Registry. Patients who received other types of drug eluting stents were not eligible for the registry. From 10 March 2003 to 11 July 2003, ninety seven consecutive patients were treated for ST elevation acute myocardial infarction with at least one PES. One patient was excluded from the analysis as his acute myocardial infarction was secondary to subacute thrombosis.
Results: Seventy-eight patients underwent primary PCI while the remainder were treated following failed thrombolytic therapy. Multi vessel disease was present in 39% of patients, with an average of 1.26 vessels treated per patient. The RCA and LAD accounted for 44% and 39% of vessels treated respectively. Forty one percent of patients received glycoprotein IIb/IIIa inhibitors.
Subacute thrombosis was seen in one patient an hour after the index procedure while a second patient required thrombolytic therapy for new ST elevation four days after the index procedure. A further two patients developed symptoms four and six days following bifurcation stenting. These patients had angiographic evidence of subacute thrombosis. Six-month follow-up data will be available for these patients at the time of presentation.
Conclusion: This is the first study to evaluate the safety and feasibility of PES in the setting of acute myocardial infarction. Bifurcation stenting in acute myocardial infarction appears to predispose to the development of subacute stent thrombosis.

1022-81 **Short Door-to-Balloon Times With Primary Percutaneous Coronary Intervention for Acute Myocardial Infarction Improve Late Survival in Patients With Early, but Not Late Presentation**

Bruce R. Brodie, Thomas D. Stuckey, Charles J. Hansen, Debra S. VerSteeg, Denise B. Muncy, Navin Gupta, William Downey, LeBauer Cardiovascular Research Foundation and Moses Cone Heart and Vascular Center, Greensboro, NC, NC

Background: The importance of door-to-balloon time (DBT) with primary PCI for AMI is controversial.
Methods: Consecutive pts (n=2,117) with ST-segment elevation AMI treated with primary PCI were prospectively enrolled in a registry and followed clinically for 6.5 years (mean).
Results: DBT (≤1.5 vs >1.5-2 vs >2-3 vs >3 hrs) was highly correlated with in-hospital mortality (5.2% vs 7.0% vs 11.4% vs 14.2%, p<0.0001) and late cardiac mortality (23.3% vs 25.8% vs 30.0% vs 34.7%, p<0.0001). After adjusting for differences in baseline variables, DBT >2 hrs was a strong independent predictor of late mortality (OR 1.31 95% CI 1.07-1.61, p=0.008). However, prolonged DBT (>2 hrs) was associated with increased mortality only in patients presenting early (≤2 hrs) (n=891) (OR 1.32 95% CI 1.08-1.62, p=0.007), and had little effect on mortality in patients presenting late (>2 hrs) (n=1206) (OR 1.17 95% CI 0.82-1.67, p=0.39)
Conclusion: Rapid time to treatment with primary PCI improves late survival in patients presenting early but is less critical in patients presenting late. These data are consistent with previous observations that there is a window of opportunity during which early reperfusion with primary PCI can result in superior outcomes, after which further delays in treatment have much less effect on mortality. These observations have implications regarding the triage of patients for primary PCI.



1022-82 **A Prospective, Randomized Trial of Mild Hypothermia During Primary Percutaneous Intervention for Acute Myocardial Infarction (COOL-MI): One-Year Clinical Outcome**

Simon R. Dixon, David G. Rizik, John J. Griffin, Joseph P. Carrozza, Barry D. Rutherford, Adnan Kastrati, Suku T. Thambar, Richard E. Kuntz, Raymond J. Gibbons, Jeffrey J. Popma, William W. O'Neill, The COOL-MI Investigators, William Beaumont Hospital, Royal Oak, MI, Sentara Virginia Beach General Hospital, Sentara, VA

Background: Mild hypothermia reduces infarct size in experimental models of acute myocardial infarction (AMI). We conducted a prospective, randomized trial to evaluate the safety and efficacy of mild hypothermia as an adjunct to primary percutaneous coronary intervention (PCI) for AMI.
Methods: Three hundred-fifty seven patients with acute ST-segment elevation MI (<6-hours from symptom-onset) were assigned to undergo primary PCI with or without adjunctive cooling. Hypothermia was induced using the Reprieve^{TM} Endovascular Temperature Therapy System (Radiant Medical Inc., Redwood City, CA). Patients were cooled to a target core temperature of 33^{o}C for 3 hours after reperfusion. The primary effectiveness endpoint of the trial was final infarct size at 30-days measured using ^{99m}Tc-sestamibi SPECT imaging. The primary safety endpoint was major adverse cardiac events (MACE) at 30-days. Clinical follow-up was performed at 6 and 12-months.
Results: One hundred seventy-seven patients were randomized to PCI with adjunctive hypothermia. The mean duration of cooling before reperfusion was 18 minutes (mean core temperature at first balloon inflation = 35^{o}C). 72% patients reached the target core temperature (mean time to target = 75 minutes). Cooling was well tolerated. There were no significant adverse clinical events related to endovascular cooling. Final infarct size in the hypothermia group was not significantly different from the control group (14.1% vs. 13.8%, p=0.83). MACE at 30-days was similar in both groups (cooling 6.2% vs. control 3.9%, p=0.45). Patients with anterior infarction who had a core temperature of <35^{o}C at reperfusion had a significantly smaller infarct size compared to both those patients with a temperature ≥35^{o}C at reperfusion (9.3% vs. 21.9%, p=0.01), and controls (9.3% vs. 18.2%, p=0.05). Late clinical follow-up is in currently progress.
Conclusion: Endovascular cooling is safe and well tolerated during mechanical reperfusion for AMI. One-year clinical outcome data will be presented for the overall patient population, and the anterior infarct subgroup with a temperature <35^{o}C at reperfusion in which a reduction in infarct size was observed.

1022-83 **The Impact of Insulin-Requiring Diabetes Mellitus on Effectiveness of Reperfusion and Outcome of Patients Undergoing Primary Percutaneous Coronary Intervention for Acute Myocardial Infarction**

David Antoniucci, Renato Valenti, Angela Migliorini, Guido Parodi, Guia Moschi, Gentian Memisha, Giovanni M. Santoro, Giampaolo Cerisano, Careggi Hospital, Florence, Italy

Background Diabetes mellitus (DM) independently predicts mortality after thrombolytic therapy for acute myocardial infarction (AMI), while previous studies on outcome of diabetics undergoing primary percutaneous coronary intervention (PCI) for AMI did not confirm the relationship between DM and mortality.
Methods The relationship between DM and six-month clinical outcome was assessed in a series of 1,071 patients with AMI who underwent primary PCI. DM was considered present if the diagnosis had been done before admission. Patients with DM were categorized based on insulin/noninsulin treatment. The efficacy of reperfusion was assessed by ST-segment resolution analysis at 30 min after infarct artery recanalization.
Results Out of 1,071 patients, 903 (84%) were non-DM and 168 had DM (16%). Among DM patients, 86 (51%) patients had insulin-requiring DM. Insulin-requiring DM patients had a worse risk profile as compared to the one of the other groups. Insulin-requiring DM patients were older, more frequently women, had a greater incidence of cardiogenic shock, 3-vessel disease and chronic occlusion. Primary PCI success was 97% in non-DM patients, 98% in insulin-requiring DM patients and 94% in non-insulin-requring DM patients. Early ST-segment resolution rate was lower in insulin-requiring DM patients (52%) as compared to the other DM patients (78%), and non-DM patients (76%; p < 0.001). The 6-month mortality rate was 26% in insulin-requiring DM patients, 7% in non-DM patients, and 4% in non-insulin-requiring DM patients (p < 0.001). Multivariate analysis showed insulin-requiring DM to be independently related to the risk of death (HR 1.94, 95% CI 1.17-3.21, p = 0.010).**Conclusions** Insulin-requiring DM is a strong predictor of mortality in patients undergoing PCI for AMI, and this relationship may be explained by a less effective myocardial reperfusion despite mechanical restoration of a normal epicardial flow in most patients.

1022-84 **Survival Benefits of Primary Angioplasty Over Thrombolysis After Adjustment for Percutaneous Transluminal Coronary Angioplasty Related Time Delay**

Giuseppe Tarantini, Angelo Ramondo, Massimo Napodano, Paolo Buja, Giambattista Isabella, Claudio Bilato, Renato Razzolini, Sabino Iliceto, University of Padua, Padua, Italy

Time to treatment remains a critical determinant of outcome after acute myocardial infarction regardless of the strategy of reperfusion used. We investigated the relationship between primary angioplasty (PTCA)-related delay and the benefits of PTCA, by reviewing the results of randomized trials comparing PTCA with thrombolytic therapy (Rx). The SHOCK trial was not considered in our analysis, Akhras's trial was excluded because the full data set was not available. DANAMI 2 study was considered as two separated substudies (invasive and referral centers). We calculated the following:
PTCA - related delay = median "door to balloon" time – median "door to needle" time
Survival benefit= 30 day mortality after Rx – 30 day mortality after PTCA. Relationship between delay and benefit was assessed by linear regression. Reported PTCA - related